

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FILED
Jan 13, 2025, 9:30 AM
in the Clerk's Office
U.S. District Court,
EDNY, Brooklyn
Pro Se Office via
Box.com

UNITED STATES OF AMERICA,

Plaintiff,

v.

ANDREW SINCLAIR /
B4B EARTH TEA LLC /
B4B CORP,

Defendants.

DATE: 1/11/2025

AFFIDAVIT OF ANDREW
MARTIN SINCLAIR
Case No.: 22-CV-1159

AFFIDAVIT IN SUPPORT OF RESPONSE TO REBUTTAL EXPERT REPORTS

I, Andrew Martin Sinclair, being duly sworn, do hereby declare and affirm as follows:

1. Introduction

I am the Defendant in the above-captioned matter and submit this affidavit to provide additional evidence in response to paragraph 3 of the rebuttal report provided by Dr. James P. McCormac. This affidavit addresses concerns regarding the delivery mechanism and efficacy of B4B Earth Tea Immune Support Drink when consumed.

2. B4B Earth Tea Immune Support Drink Delivery Mechanism

B4B Earth Tea is a natural dietary supplement designed to support immune function. Upon ingestion, its plant-based active compounds are absorbed via the gastrointestinal system. These bioavailable compounds interact with the immune system and are utilized by the body's natural processes.

The tea's synergistic blend of herbs and plants differs from pharmaceutical drugs, which deliver isolated compounds, by supporting immune health through holistic mechanisms.

3. Additional Scientific Evidence Supporting Delivery and Efficacy

Dr. McCormac has claimed that “in vitro studies do not replicate or demonstrate what would go on with a compound when it is put inside a human body.” I submit that the ELISA immune cytokine study demonstrates significant immune-modulatory effects in vitro. While in vitro studies may not fully replicate the body’s complex processes, when combined with user feedback and observations, they support the claim that B4B Earth Tea promotes immune function upon ingestion.

3a Report documents

All Ray Biotech data are submitted as received.

4. Systematic Bias

The plaintiff has labeled me a liar, despite possessing undercover records and firsthand knowledge of the product’s positive effects. Their actions demonstrate systematic bias:

- They dismiss credible scientific evidence while ignoring the FDA’s guidance on the value of in vitro studies in evaluating product efficacy and safety.
- Since April 2020, the plaintiff has not initiated or mentioned the Structure/Function claims process, choosing instead to undermine the product without objective evaluation.

5. Importance of In Vitro Studies

In vitro studies are acknowledged by the FDA and other regulatory authorities as indispensable tools for assessing pharmacological and toxicological effects. They provide critical insights that inform clinical decision-making and regulatory approvals.

- FDA Guidance on Nonclinical Testing: The FDA explicitly states that in vitro studies are essential for understanding mechanisms of action, identifying potential risks, and guiding regulatory decisions. <https://www.fda.gov/media/72260/download>.
- Oncology Drug Products: In vitro diagnostic tests have a pivotal role in supporting regulatory approval of oncology drugs by ensuring the precision and reliability of therapeutic approaches. <https://www.fda.gov/media/169616/download>.

6. Plaintiff’s Dismissal of In Vitro Success

Despite FDA guidance emphasizing the importance of in vitro data, the plaintiff dismisses the ELISA COVID-19 Spike ACE2 study as irrelevant. This inconsistency undermines their position and highlights their bias against my product.

7. Conclusion

In vitro studies form a critical foundation for product evaluation, as outlined by FDA guidelines. Although they are not standalone measures, they provide essential data to support efficacy and safety. The plaintiff's rejection of this evidence contradicts established scientific principles and further demonstrates their prejudiced approach.

Date: JANUARY 11, 2025

Signature:  _____

Andrew Martin Sinclair

Defendant, Pro Se

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NOTARY ACKNOWLEDGMENT

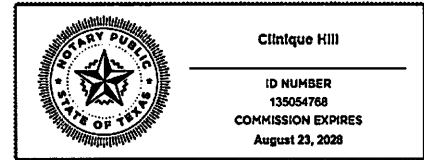
State of [Texas]

County of [Denton]

On this 13th day of January, 2025, before me, [], a Notary Public in and for said State, personally appeared Andrew Martin Sinclair, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged that he executed the same for the purposes therein contained.

In witness whereof, I hereunto set my hand and official seal.

Notary Public My Commission Expires: 08/23/2028



Electronically signed and notarized online using the Proof platform.

Clinique Hill